



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MARYLAND 21702-5012

REPLY TO
ATTENTION OF:

MCMR-ZA

23 APR 2003

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: U.S. Army Medical Research and Materiel Command (USAMRMC) Title 21 of the Code of Federal Regulations (21 CFR) Part 11 Steering Committee

1. I hereby appoint the following individuals to my 21 CFR Part 11 Steering Committee:

Name	Position
COL Jeffrey Davies	Chair and Deputy Commander, USAMRMC
COL Ralf Brueckner	MeRITS Project Manager, USAMRMC
COL Denise McCollum	Deputy for Resource Management, USAMRMC
COL Jeffrey Gere	Commander, USAMMDA
COL Charles McQueen	Commander, WRAIR
COL Erik Henschel	Commander, USAMRIID
COL Laura Brosch	Deputy for Regulatory Compliance and Quality, USAMRMC
LTC James Crowther	Deputy for Information Management and Information Technology, USAMRMC
Mr. William Howell	Deputy for Acquisition and Advanced Development, USAMRMC
Ms. Phylis Rinehart	Deputy Chief of Staff for Information Management, USAMRMC

Additional members (permanent, ad hoc, advisory) may be appointed or invited as required. If an individual is no longer functioning in a position listed above, their replacement will serve on this committee.

2. Responsibilities include:

a. Assist the MeRITS Project Management Office (PMO) in developing the Commanding General's (CG's) Command policy on 21 CFR Part 11.

b. Assist the MeRITS PMO in developing and executing the USAMRMC 21 CFR Part 11 Corrective Action Plan.

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- c. Provide leadership and communicate the CG's vision to USAMRMC organizations regarding 21 CFR Part 11.
 - d. Monitor USAMRMC's progress towards 21 CFR Part 11 compliance.
 - e. Provide guidance to the MeRITS PMO.
 - f. Assist the MeRITS PMO in making risk-remediation prioritizations and decisions.
 - g. Examine current business practices and organizational structure and responsibilities regarding 21 CFR Part 11 and work towards improving business efficiencies.
 - h. Act as dispute-resolution group on 21 CFR Part 11 issues for USAMRMC.
3. The committee will serve for a period of one year and be extended as needed.
4. The POC is COL Jeffrey Davies. He can be reached at 301-619-7378, DSN 343-7378, or e-mail: jeffrey.davies@amedd.army.mil.



LESTER MARTINEZ-LOPEZ
Major General, MC
Commanding

DISTRIBUTION:

COL Jeffrey Davies
✓ COL Ralf Brueckner
COL Denise McCollum
COL Jeffrey Gere
COL Charles McQueen
COL Erik Henchal
COL Laura Brosch
LTC James Crowther
Mr. William Howell
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